

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a MCAN under this part, the manufacturer, importer, or processor must immediately cease distributing the microorganism to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a MCAN under this part and the MCAN review period has ended.

(ii) The recipient has submitted a MCAN under this part and the MCAN review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

§ 725.912 Exemptions.

Persons identified in § 725.105(c) are not required to submit a MCAN under subpart D of this part for a microorganism identified in subpart M of this part, unless otherwise specified in a specific section in subpart M, if:

(a) The person submits a MCAN for the microorganism prior to the promulgation date of the section in subpart M of this part which identifies the microorganism, and the person receives written notification of compliance from EPA prior to the effective date of such section. The MCAN submitter must comply with any applicable requirement of section 5(b) of the Act. The MCAN must include the information and test data specified in section 5(d)(1) of the Act. For purposes of this exemption, the specific section in subpart M of this part which identifies the microorganism and §§ 725.3, 725.15, 725.65, 725.70, 725.75, 725.100, and 725.900 apply; after the effective date of the section in subpart M of this part which identifies the microorganism, §§ 725.105 and 725.910 apply and § 725.920 continues to apply. EPA will provide the MCAN submitter with written notification of

compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the MCAN will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances, or

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart M of this part which identifies the microorganism.

(b) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart M of this part, abiding by the provision of the section 5(e) order exempts the person from submitting a MCAN for that specific significant new use.

§ 725.920 Exports and imports.

(a) *Exports.* Persons who intend to export a microorganism identified in subpart M of this part, or in any proposed rule which would amend subpart M of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at part 707 of this chapter.

(b) *Imports.* Persons who import a substance identified in a specific section in subpart M of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR §§ 12.118 through 12.127 and 127.28(i). The EPA policy in support of the import certification requirements appears at part 707 of this chapter.

§ 725.950 Additional recordkeeping requirements.

Persons submitting a MCAN for a significant new use of a microorganism must comply with the recordkeeping requirements of § 725.65. In addition, the following requirements apply:

(a) At the time EPA adds a microorganism to subpart M of this part, EPA may specify appropriate recordkeeping requirements. Each manufacturer, importer, and processor of the